

REMARKS

Upon entry of this preliminary amendment, this application will contain claims 1-14 pending and under consideration. Entry of the above amendment prior to the examination of this application and passage of this application to issuance are respectfully requested. Applicants submit with the application that accompanies this preliminary amendment a check in payment of the statutory fee that is based upon the status of the claims after entry of this amendment. Applicants respectfully request consideration of this application and preliminary amendment, and passage of this application to allowance.

Respectfully submitted,

By: Thomas Q. Henry
Thomas Q. Henry, Reg. No. 28,309
Woodard, Emhardt, Naughton
Moriarty & McNett
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456
Fax No. (317) 637-7561

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 5, 6, 11, 12, 13 and 14 have been amended as follows:

5. (Amended) The pharmaceutical material of [any of] claim[s] 2 [to 4] in which the active pharmaceutical ingredient comprises discrete units and the units are included within the crystals in isolation from one another.

6. (Amended) The pharmaceutical material of [any of] claim[s] 2 [to 5] in which the active pharmaceutical ingredient is included within the crystal at a concentration of about 0.001 to 1 weight percent based on the weight of the crystal including the active pharmaceutical ingredient.

11. (Amended) The invention of [any of] claim[s] 1 [to 10] in which, for each crystal, the active pharmaceutical ingredient is included within the crystal in a growth-sector specific orientation.

12. (Amended) The invention of [any of] claim[s] 1 [to 11] and further comprising a pharmaceutically-acceptable adjuvant selected from the group consisting of excipients, diluents, carriers and mixtures thereof.

13. (Amended) The invention of [any of] claim[s] 1 [to 12] in which the active pharmaceutical ingredient is a biopharmaceutical.

14. (Amended) The invention of [any of] claim[s] 1 [to 13] in which the crystal lattice component is selected from the group consisting of: sucrose, lactose, trehalose, maltose, galactose, sorbose, mannitol, lactitol, sorbitol, glycine, alanine, lysine, arginine, ascorbic acid, nicotinamide, thiamine, adenine, pyridoxine hydrochloride, caffeic acid, vanillic acid, ferulic acid, benzoate, sorbate, methyl paraben, sodium ascorbate, sodium saccharine, potassium citrate, zinc, calcium, and any derivatives, salt forms, or mixtures thereof.